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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,509	09/28/2001	Harry S. Sowden	MCP-0293	5303
27777	7590	02/26/2003	EXAMINER	
AUDLEY A. CIAMPORCERO JR. JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PULLIAM, AMY E	
		ART UNIT	PAPER NUMBER	
		1615		

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/966,509 Examiner Amy E Pulliam	SOWDEN ET AL. Art Unit 1615
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
<b>Period for Reply</b> <p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b> <p>1)<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>03 February 2003</u>.</p> <p>2a)<input type="checkbox"/> This action is FINAL.                  2b)<input type="checkbox"/> This action is non-final.</p> <p>3)<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</p>		
<b>Disposition of Claims</b> <p>4)<input checked="" type="checkbox"/> Claim(s) <u>1-39</u> is/are pending in the application.</p> <p>4a) Of the above claim(s) _____ is/are withdrawn from consideration.</p> <p>5)<input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6)<input type="checkbox"/> Claim(s) _____ is/are rejected.</p> <p>7)<input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8)<input checked="" type="checkbox"/> Claim(s) <u>1-39</u> are subject to restriction and/or election requirement.</p>		
<b>Application Papers</b> <p>9)<input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10)<input type="checkbox"/> The drawing(s) filed on _____ is/are: a)<input type="checkbox"/> accepted or b)<input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11)<input type="checkbox"/> The proposed drawing correction filed on _____ is: a)<input type="checkbox"/> approved b)<input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12)<input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>		
<b>Priority under 35 U.S.C. §§ 119 and 120</b> <p>13)<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a)<input type="checkbox"/> All    b)<input type="checkbox"/> Some * c)<input type="checkbox"/> None of:      1.<input type="checkbox"/> Certified copies of the priority documents have been received.      2.<input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.      3.<input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>* See the attached detailed Office action for a list of the certified copies not received.</p> <p>14)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</p> <p>a)<input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15)<input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>		
<b>Attachment(s)</b> <p>1)<input type="checkbox"/> Notice of References Cited (PTO-892)      2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)      3)<input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .</p> <p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____.      5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)      6)<input type="checkbox"/> Other:</p>		

## DETAILED ACTION

### *Receipt of Papers*

Receipt is acknowledged of the Information Disclosure Statement received February 11, 2002, the Supplemental IDS and Preliminary Amendment, received March 20, 2002, the Declaration and Extension of Time, received March 12, 2002m, the Drawings, received May 13, 2002, the Second Supplemental IDS, received April 15, 2002, and the Third Supplemental IDS, received February 3, 2003.

### *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a method of forming compressed dosage forms, classified in class 264, subclass 109+.
- II. Claims 13-27, drawn to apparatuses for forming compressed dosage forms, classified in class 425, subclass 406+, 418,451.5.
- III. Claims 28-39, drawn to compressed dosage forms, classified in class 424, subclass 464.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and III are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case, there are several well known

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methods of creating solid dosage forms, many of which use an apparatus which is different than the ones claimed by Applicant. Applicant himself states, on page 1, line 31, that there are various apparatuses employed in creating the different solid dosage forms which are known in the pharmaceutical art.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, similar to the discussion above, there are many different processes known for the creation of solid dosage forms. Furthermore, the process of compression molding is well known in the art, and has been used with a variety of apparatuses.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, also similar to the discussion above, compressed solid dosage forms are well known in the pharmaceutical art, and clearly there are known processes utilized in making the dosage forms.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

*Election of Species*

This application contains claims directed to the following patentably distinct species of the claimed invention: Different apparatuses. Claims 13-20 are drawn to an apparatus for forming compressed dosage forms, comprising a suction source, a die cavity with two ports, a filter and a punch. Claims 21-26 are drawn to an apparatus for forming compressed dosage forms, comprising a die table having a plurality of die cavities therein, punches aligned with the die cavities, and rollers aligned with the rows of die cavities. Claim 27 is drawn to a rotary compression module for forming compressed dosage forms, comprising a single fill zone, a single compression zone, a single ejection zone, a circular die tablet, and punches. Each of these apparatuses requires different features, and therefore the apparatuses are considered patentably distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam  
Patent Examiner  
AU 1615  
February 24, 2003

*AS*  
A. S. Pulliam, PhD  
Patent Examiner  
Feb 24, 2003